

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Gerhardt Kumpe et al.)	Group Art Unit: 1656
)	
Application No.: 10/670,563)	Examiner: Agnes Beata Rooke
)	
Filed: September 26, 2003)	
)	
For: CONCENTRATE OF A FACTOR)	Confirmation No.: 8137
VIII:C-CONTAINING VON)	
WILLEBRAND FACTOR AND THE)	
PROCESS RELATING THERETO)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. § 1.132

I, Gerhardt Kumpe, do hereby make the following declaration:

1. I am one of the named Applicants of the above-identified application and am one of the co-inventors of the subject matter described and claimed therein.
2. I have read and understood U.S. Patent Application No. 10/670,563.
3. I have been informed that claims 1-13 and 15-24 are pending in U.S. Patent Application No. 10/670,563.
4. I have examined claims 1-13 and 15-24 of U.S. Patent Application No. 10/670,563 and I believe that I am a joint inventor of the subject matter of those claims.
5. I am a coauthor of a publication identified as Heimburger N. et al., "Factor VIII Concentrate, Highly-Purified and Heated in Solution," Drug Res., 31 (I), No. 44, 619-622 (1981) ("Heimburger et al.").

6. I have been informed that Heimbürger et al. has been cited by the U.S. Patent and Trademark Office against claims 10-13, 15, and 19-24 in U.S. Patent Application No. 10/670,563.

7. The experimental work described in Heimbürger et al. was performed under my direction or supervision.

8. The concentrations of glycine and NaCl used in the fractional precipitation described in Heimbürger et al. were 128.3 g/l and 122.2 g/l, respectively.

9. As summarized in Exhibit A (attached), U.S. Patent Application No. 10/670,563 teaches the unexpected discovery that in order to reproducibly generate a concentrate of a factor VIII:C-containing von Willebrand factor (vWF/FVIII:C) in which the ratio of von Willebrand factor ristocetin cofactor activity (vWF:RCoF) to von Willebrand factor antigen (vWF:Ag) is greater than 1, the fractional precipitation should use concentrations of glycine less than or equal to 110 g/l. In contrast, Heimbürger et al. used glycine concentrations above 110 g/l and did not obtain a vWF:RCoF to vWF:Ag ratio greater than 1.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 25. Februar 2008

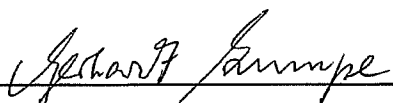
By: 

EXHIBIT A

Source of Data	NaCl g/l	Glycine g/l	vWF:RCoF/vWF:Ag
Heimbürger et al.	122.2	128.3	<1
Specification Example 1 batch A	122	80	3.6
Specification Example 1 batch B	122	90	2.4
Specification Example 1 batch C	122	100	2.4
Specification Example 2 batch A 1 st precipitation	122.2	71.1	3.0
Specification Example 2 batch A 2 nd precipitation	122.2	160	1.1
Specification Example 2 batch B 1 st precipitation	122.2	90.4	1.6
Specification Example 2 batch B 2 nd precipitation	122.2	160	0.63
Specification Example 2 batch C; 1 st precipitation	122.2	109.6	1.6
Specification Example 2 batch C 2 nd precipitation	122.2	160	0.26
Specification Example 3 batch 1 1 st precipitation	122.2	128.3	0.9
Specification Example 3 batch 1 2 nd precipitation	122.2	160	0.3

Source of Data	NaCl g/l	Glycine g/l	vWF:RCoF/vWF:Ag
Specification Example 3 batch 2	122.2	128.3	0.7
Specification Example 3 batch 3	122.2	128.3	0.9
Specification Example 3 batch 4	122.2	128.3	0.8
Specification Example 4 batch 1 1 st precipitation	122.2	128.3	0.9
Specification Example 4 batch 1 2 nd precipitation	122.2	160	0.9
Specification Example 4 batch 2 1 st precipitation	151.5	66.7	1.3
Specification Example 4 Batch 2 2 nd precipitation	151.5	160.0	0.6